DEPARTMENT OF HEALTH & HUMAN SERVICES

95107d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3001239019

December 6, 2004

Pat R. Mitchell
President
California Natural Products
1250 East Lathrop Road
Lathrop, CA 95330

WARNING LETTER

Dear Mr. Mitchell:

On July 19-23, 27, and August 2, 2004, we inspected your food manufacturing facility located at 1250 East Lathrop Road, Lathrop, CA 95330 and your food distribution warehouse located at 15789 McKinley Street, Lathrop, CA 95330. We found that you had serious deviations from the Low-acid Canned Food regulations in Title 21 of the Code of Federal Regulations, Parts 108 and 113 (21 CFR Parts 108 and 113). Specifically, you deviated from Section 113.40(g)(2)(ii)(b) by failing to adequately segregate and handle, in accordance with Section 113.89, product packaged under conditions below those specified in the scheduled process. You experienced a loss of sterility and then shipped some of the production without first obtaining an evaluation by a competent processing authority that was adequate to detect any potential hazard to public health. Failure to comply with all of the requirements of 21 CFR Part 108.35 and the mandatory portions of Part 113 constitutes a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, such failure renders your Low-acid Canned Food adulterated within the meaning of section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4). Some of your almond-based, soy-based, and rice-based products are adulterated under section 402(a)(4) in that these products were processed, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. The introduction or delivery for introduction of an adulterated food into interstate

commerce is a violation of section 301(a) of the Act. You can find the Act and the Low-acid Canned Food regulations through links in FDA's home page at http://www.fda.gov.

21 CFR 113.89 requires that processing deviations be addressed in the manner specified by that section before a decision is made to ship a food in normal distribution. Specifically, the affected product must either be fully reprocessed, or set aside for an evaluation by a competent processing authority that is adequate to detect any potential hazard to public health. Unless the evaluation demonstrates that the product has been given a thermal process that rendered it free of microorganisms of potential public health significance, the product shall be either fully reprocessed to render it commercially sterile or destroyed.

From March 8 to March 22, 2004, your firm lost sterility in the aseptic zone of filler #1 [redacted]). Subsequently, your firm determined that sterile product had backed up into the sterile air line. It appears that product lodged in the air line between the CIP connection and the incinerator became contaminated with microorganisms and in turn caused product to be filled under non-aseptic conditions. The conditions within the filler did not meet commercial sterility during production of low acid products during this time period.

To properly evaluate these processing deviations, a processing authority would have had to determine if the sterile air line pre-sterilization process rendered the line commercially sterile during the period of production affected. Given the inability to define what conditions existed during the production period in question, it is unlikely that a proper evaluation of the processing deviations could have been conducted.

Your firm responded to its discovery of the loss of commercial sterility in filler #1 by examining affected product, discarding portions of the production exhibiting swollen containers, and distributing the remaining product. FDA does not consider this response to meet the requirements of 21 CFR 113.89. An appropriate response would have been to evaluate the actual processing conditions within the sterile air line and the [redacted] aseptic filling and packaging machine, if possible, or to destroy or reprocess the affected product. As a result of your firm's failure to do so, your firm shipped product involved in processing deviations without having an evaluation made by a competent processing authority in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health.

At the conclusion of the inspection, these and other observations were listed on Form FDA 483, Inspectional Observations, which was issued to and discussed with William J. Tipton, Executive Vice President. A copy of this form is enclosed for your ready reference.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA.

You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure, injunction and/or issuance of an Order of Need to obtain and hold a Temporary Emergency Permit.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violations. We acknowledge the firm-initiated recall of affected products which you initiated on September 9, 2004 (Class II Recall No. F-454-4) and correspondence you have had with our district recall coordinator. If you cannot complete all corrections before responding, we expect you will explain the reason for any delay and the time period within which the corrections will be completed.

Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions regarding any issue in this letter, you may contact Mr. Peterson at (510) 337-6856.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosure: Form FDA 483